



UNITED STATES PATENT AND TRADEMARK OFFICE

7
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,070	08/22/2003	Michael Wayne Graham	546322000303	8796
32042	7590	01/24/2008		
PATTON BOGGS LLP 8484 WESTPARK DRIVE SUITE 900 MCLEAN, VA 22102			EXAMINER WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,070	GRAHAM ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48, 107, 110, 111, 114-136, 138-140 and 145-152 is/are pending in the application.
- 4a) Of the above claim(s) 139, 140, 145 and 150-152 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48, 107, 110, 111, 114-136, 138, 146-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/29/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/07 has been entered.

Election/Restrictions

Newly submitted claim 150-152 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: see restriction mailed on 10/15/04.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 150-152 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 139, 140, and 145 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/15/04.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/29/07 was filed after the mailing date of the Final Rejection on 4/27/07. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Some of the articles or documents listed on the information disclosure statement filed 10/29/07 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because several of the journal articles are missing the title and several documents are missing a publication date. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

Claims 107 and 111 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 107 recites that the structural region genes are separated by a sequence of nucleotides. However, claim 107 depends on claim 48 (claim 111 depends on claim 110), which recites that the structural region genes are arranged as

an interrupted palindrome sequence. The term "interrupted palindrome sequence" indicates that there is already a sequence of nucleotides between the genes.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48, 107, 110, 111, 114-136, 138, and 146-149 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48, 107, 110, 111, 114-136, 138, and 146-149 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how a gene comprising two identical sequences to a target gene in a vertebrate animal cell can also be arranged as an interrupted palindrome sequence. An interrupted palindrome sequence is a sequence and its complement, not two identical sequences, wherein one sequence is in the direct orientation and the other sequence is inverted. The instant specification only recites the term and does not specifically define the term. See page 29. The skilled artisan understands the term as described above. See Abdurashitov et al. Nucleic Acids Res. 1997, 25, abstract only. See also MPEP 2173.02, which recites: Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claim 119 recites the limitation "wherein the viral vector is a retrovirus or lentivirus" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claim depends from claim 116 which does not recite the limitation, however, claim 118 does recite the limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The term "arranged in the structural gene region in an interrupted palindrome sequence" in the limitation recited in instant claims 48, 110, 133, and claims dependent therefrom reads on arranging the copies of nucleotide sequences in sense and antisense orientation in the synthetic gene with nucleotides (e.g., stuffer) between the nucleotide sequences. The instant specification only recites the term and does not specifically define the term. See page 29. The skilled artisan

understands the term as described above. See Abdurashitov et al. Nucleic Acids Res. 1997, 25, abstract only. See also MPEP 2173.02, which recites: Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Furthermore, in view of the 112 second paragraph rejection and the term "structural gene region placed in the antisense orientation" in claims 48, 107, 110, 111, 133, 136, and 138; the term could read on antisense nucleotide sequence.

Claims 48, 107, 108, 110, 111, 114, 115, 116, 117, 118, 120, 121, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, and 146-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al (US 6,506,559, cited on a PTO-1449). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising dsRNA comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The structural gene can comprise one or more strands of the nucleotide sequence (column 4). The dsRNA may be formed by a single self-complementary RNA strand or two complementary RNA strands (column 7). The construct comprises a regulatory region including polyadenylation (columns 8-9). The nucleotide sequence may be at least 25 or 50 bases (column 8). The vector can be introduced into a cancerous cell, including cancer cells found in humans and stem cells (column 8-10). A viral vector or lipid mediated carrier transport can be used as the vector (column 9). The cell can comprise a target gene at risk from a pathogen including HIV or

can be from several different types of animals (columns 4, 8, and 10). The target gene can be an endogenous from in a human cell (columns 4 and 10-11). The construct can comprise a structural gene with an intron. In addition, the structural gene can comprise a 5' or 3' untranslated region (column 20).

Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive.

In response to applicant's argument that "two complementary strands" that Fire discloses are by definition a sequence and its complement and are not the same as multiple copies of an identical sequences, the argument is not found persuasive because the terms "antisense orientation" and "interrupted palindrome sequence" read on a sequence and its complement. See Abdurashitov et al (*supra*) for the term "interrupted palindrome sequence".

In response to applicant's argument that examiner has not pointed out to any disclosure of a stuffer fragment in Fire, the argument is not found persuasive because a self-complementary sequence would indicate a hairpin structure that would require a loop. The loop would separate the two sequences and would read on a stuffer sequence.

In response to applicant's argument that the examiner explicitly stated in the last office action that Fire does not specifically teach separating a construct comprising the structural gene sequences with a stuffer sequence, the argument is not found persuasive because the examiner's statement was taken out of context. The examiner was referring to dependent claims that specifically recite the length of the stuffer fragment. Compare the listing of claims for the 102(e) rejection and the 103(a) rejection in the prior office action.

In response to applicant's argument that the use of stuffer fragment has led to unexpectedly beneficial effects in production and use of the claimed invention, the argument is not found persuasive because other than applicant's assertion, there is no evidence of record to support assertion. "The arguments of counsel cannot take the place of evidence in the record." See *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

In response to applicant's argument that Fire patent does not enjoy priority to the provisional cited in the patent because the provisional does not disclose a construct comprising multiple structural gene regions, wherein the regions consist of greater than 20 consecutive nucleotides and gene regions placed in sense orientation and antisense orientation are arranged as interrupted palindrome sequence, the argument is not found persuasive because Fire teaches nucleotide sequences comprising one or more strands of nucleotides and an expression vector producing the dsRNA (the expression of the claimed product results in the same dsRNA). As stated above, the terms "antisense orientation" and "interrupted palindrome sequence" read on a sequence and its complement. Fire teaches dsRNA, wherein each strand is greater than 20 consecutive nucleotides (page 27 of provisional).

The Declarations filed on 10/29/07 under 37 CFR 1.131 have been considered but are ineffective to overcome the reference.

The 102(e) reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the

reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718. In addition, the Declarations are directed to a different application (90/007247) with a different claim set.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48, 110, 116, 117, 119, 122, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire taken with Dietz (US 5,814,500). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising dsRNA comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The dsRNA may be formed by a single self-complementary RNA strand or two complementary RNA strands (column 7). The construct comprises a regulatory region including polyadenylation (columns 8-9). The nucleotide sequence may be at least 25 or 50 bases (column 8). The vector can be introduced into a cancerous cell, including cancer cells found in humans (column 9-10). A viral vector or lipid mediated carrier transport can be used as the vector (column 9). The cell can comprise a target gene at risk from a pathogen including HIV or can be from several different types of animals (columns 4, 8, and 10). The target gene can be an endogenous from in a human cell (columns 4 and 10-11). The construct can comprise a structural gene with an intron. In addition, the structural gene can comprise a 5' or 3' untranslated region (column 20). The structural gene can comprise one or more strands of the nucleotide sequence (column 4). However, Fire does not specifically teach a retroviral vector comprising the dsRNA construct.

However, at the time the invention was made, Dietz teaches making a retroviral vector for expressing inhibiting RNA (column 8). Dietz further teaches using a SV40 early, RSV or CMV promoter to express the RNA (column 6).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Dietz, namely to produce a

retroviral vector comprising the dsRNA construct. One of ordinary skill in the art would have been motivated to combine the teaching for integration of the dsRNA into the genome of an animal cell.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Dietz, namely to produce a dsRNA construct comprising a CMV, SV40 early, or RSV promoter. One of ordinary skill in the art would have been motivated to combine the teaching to sufficiently express the dsRNA in animal cells.

In view of Fire and Dietz, one of ordinary skill in the art would have had a reasonable expectation of success for producing the product

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive for the reasons set forth in the response to applicant's arguments under the 102 (e) rejection using Fire.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is the case here. The totality of the prior art of record teaches using a nucleotide sequence to separate a nucleotide sequence in a vector for cloning purposes or isolating a nucleotide sequence. "The combination

of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." See *KSR v. Teleflex*, 550 U.S. ___, 127 S. Ct. 1727 (2007).

Applicant argues that antisense art is not analogous to siRNA technology. Contrary to applicant's assertion, antisense art is certainly considered analogous to siRNA technology and is considered to be in the same field as applicant's endeavor and reasonably pertinent to the particular problem, which in the instant case is delivery of sequence specific nucleic acid therapeutics (see Fire, US 6,506,559).

In response to applicant's argument that the office action mailed on 4/27/07 offers no technical basis for concluding that one of skill would expect success in an interrupted palindrome sequence, the argument is not found persuasive because Fire teaches using viral vectors to product the dsRNA and retroviral vectors are well known in the prior art for expression desired nucleotide sequences. "The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success." See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See also *KSR v. Teleflex*, 550 U.S. ___, 127 S. Ct. 1727 (2007).

Claims 133, 136, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al (US 6,506,559, cited on a PTO-1449) taken with Ladner et al (US 5,198,346). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). A viral vector can be used as the vector (column 9). However, Fire does not specifically teach separating a construct comprising the structural gene sequences with a stuffer sequence.

However, at the time the invention was made, Lander teaches using a stuffer fragment having above about 10 nucleotides to introduce a stop codon or a unique restriction site (column and Table 704).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Ladner, namely to produce a construct comprising a structural gene with a stuffer sequence having above about 10 nucleotides. One of ordinary skill in the art would have been motivated to combine the teaching to introduce a termination site after the sense strand or a unique restriction sequence for cloning purposes.

In view of Fire and, one of ordinary skill in the art would have had a reasonable expectation of success for producing the product

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive for the reasons set forth in the response to applicant's arguments under the 102 rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is the case here. The totality of the prior art of record teaches using a nucleotide sequence to separate a nucleotide sequence in a vector for cloning purposes or isolating a nucleotide sequence.

In response to applicant's argument that the office action mailed on 4/27/07 offers no technical basis for concluding that one of skill would expect success in an interrupted palindrome sequence containing a stuffer, the argument is not found persuasive because Fire teaches using vectors to product the dsRNA and cloning sites are well known in the prior art for constructing vectors. "The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success." See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See also *KSR v. Teleflex*, 550 U.S. ___, 127 S. Ct. 1727 (2007).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48, 107, 110, 111, 114-121, 124-136, 138, and 146-149 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 11-15, and 19-21 of Patent No. 6,573,099. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a construct capable of producing dsRNA.

Claims 48, 107, 110, 111, 114-121, 124-136, 138, and 146-149 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56, 59, 60, 62, 63, 65-67, 77-90, 95-101, and 107 of copending Application No. 09/646,807. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims read on an animal cell comprising a construct comprising two identical sequences to a target gene in an animal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 48, 107, 110, 111, 114-121, 124-136, 138, and 146-149 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims from copending Application Nos. 10/346,853, 10/646,070, and 11/364,183. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims read on an animal cell comprising a construct comprising two identical sequences to a target gene in an animal.

Application/Control Number:
10/646,070
Art Unit: 1635

Page 16

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 6:30 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, SPE – Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Brian Whiteman/
Primary Examiner, Art Unit 1635